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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,411	03/25/2004	Toshihiro Mori	0649-0994PUS1	5118

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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02/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/808,411	MORI ET AL.	
	Examiner	Art Unit	
	FRANK W. LU	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 34-42 is/are pending in the application.
4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-15, 19-23 and 34-42 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on October 30, 2008 has been entered. The claims pending in this application are claims 1-23 and 34-42 wherein claims 16-18 have been withdrawn due to species election mailed on January 22, 2007. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on October 30, 2008. Therefore, claims 1-15, 19-23, and 34-42 will be examined.

Claim Objections

2. Claim 1 is objected to because of the following informalities: (1) "sample solution" in line 6 should be "a sample solution"; and (2) "a sample solution" in line 12 should be "the sample solution".
3. Claim 10 is objected to because of the following informality: "acetyl cellulose" should be "the acetyl cellulose".
4. Claim 11 is objected to because of the following informalities: (1) "sample solution" in line 11 should be "a sample solution"; and (2) "a sample solution" in line 18 should be "the sample solution".
5. Claim 13 or 20 is objected to because of the following informality: "sample solution" should be "the sample solution".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. New Matter

Claims 1-15, 19-23, and 34-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation “a pressure sensor capable of detecting the pressure in the accommodation part is connected to an operation part of the pressure difference-generating apparatus which extends out of the syringe” is added to the newly amended independent claims 1 and 11. Although the specification describes an apparatus for separating and purifying nucleic acids comprising (a) a solid phase, (b) a container having at least two openings for accommodating said solid phase, (c) a pressure difference generating apparatus coupled to one of the openings of said container and (d) a pressure sensor (e.g., see original filed claim 34), page 29, lines 1-6, page 27, last full paragraph, page 12, first full paragraph and Figs. 1, 2 and 4 of the specification suggested by applicant fail to define or provide any disclosure to support such claim recitation recited in claims 1 and 11 because the phrase “the pressure difference-generating apparatus which extends out of the syringe” recited in claims 1 and 11 is much broader than “the pressure difference-generating apparatus which couples to one of the openings” taught by the specification and is not limited to “the pressure difference-generating apparatus which couples to one of the openings”.

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MPEP 2163.06 notes “IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.” MPEP 2163.06 further notes “WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT “NEW MATTER” IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*” (emphasis added).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-15, 19-23, and 34-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 or 11 is rejected as vague and indefinite in view of the phrase because the phrase “a solid phase comprising an organic polymer having a hydroxyl group on the surface thereof is accommodated in said solid phase-holding member” does not make sense. Does this phrase mean a solid phase comprising an organic polymer having a hydroxyl group on the surface thereof accommodated in said solid phase-holding member? Please clarify.

11. Claim 1 or 11 is rejected as vague and indefinite in view of the phrase “a solid phase comprising an organic polymer having a hydroxyl group on the surface thereof is accommodated in said solid phase-holding member, located only at the first the solid phase being able to adsorb and desorb nucleic acids in a sample solution”. Since the claim does not require that the solid phase-holding member is inside of the cylindrical syringe, it is unclear why a solid phase

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comprising an organic polymer having a hydroxyl group on the surface can be located only at the first opening part of the cylindrical syringe. Please clarify.

12. Claims 2, 3, and 37 are rejected as vague and indefinite. Since, in view of claim 1, a cylindrical syringe and a pressure difference-generating apparatus are two different components of an apparatus for separating and purifying nucleic acids, while, in view of claims 2, 3, and 37, a cylindrical syringe and a pressure difference-generating apparatus are the same component of the apparatus for separating and purifying nucleic acids, claim 1 and claims 2, 3, and 37 do not correspond each other. Please clarify.

13. Claim 13 is rejected as vague and indefinite. Since claims 1 and 12 do not require that the accommodation part must contain a sample solution, it is unclear why the discharge of the sample solution in the accommodation part is sensed by a pressure change. Please clarify.

14. Claim 20 is rejected as vague and indefinite because it is unclear that a pressure sensor in the claim is identical to the pressure sensor in claim 1 or not. Please clarify.

15. Claim 20 is rejected as vague and indefinite. Since step (d) does not require to discharge the sample solution, it is unclear why steps (c) and (e) can start after sensing the discharge of the sample solution in steps (b) and (d), respectively. Please clarify.

16. Claim 22 is rejected as vague and indefinite because it is unclear that a pressure sensor in the claim is identical to the pressure sensor in claim 1 or not. Please clarify.

17. Claim 34 is rejected as vague and indefinite. Since claim 12 requires that adsorption and desorption of nucleic acids are performed using the apparatus recited in claim 1 while claim 34 requires that adsorption and desorption of nucleic acids are performed using an apparatus for separating and purifying nucleic acids comprising (a) the solid phase, (b) the accommodation

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part having at least two openings for accommodating said solid phase, (c) a pressure difference generating apparatus coupled to one of the openings of said accommodation part and (d) a pressure sensor, the apparatus recited in claims 12 and 34 are different. Since claim 34 is dependent on claim 12, claim 34 must use the apparatus recited in claim 1. Thus claims 12 and 34 do not correspond each other. Please clarify.

18. Claim 34 is rejected as vague and indefinite because the claim does not make sense. Does the claim mean that the pressure sensor is used to detect whether the pressure in the accommodation part has reached a certain level? Please clarify.

19. Claim 39 or 42 recites the limitation “the container that has reached a certain preset pressure” in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no phrase “container that has reached a certain preset pressure” in claims 1 and 11. Please clarify.

20. Claims 39-41 are rejected as vague and indefinite. Since, in view of claim 11, a cylindrical syringe and a pressure difference-generating apparatus are two different components of an apparatus for separating and purifying nucleic acids, while, in view of claims 39-41, a cylindrical syringe and a pressure difference-generating apparatus are the same component of the apparatus for separating and purifying nucleic acids, claim 11 and claims 39-41 do not correspond each other. Please clarify.

Response to Arguments

21. Applicant's arguments with respect to claims 1-15, 19-23, and 34-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. No claim is allowed.

24. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
February 11, 2009